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Attorney Docket No. 24299-506CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Duff *et al.*
SERIAL NUMBER: Not yet assigned EXAMINER: Not yet assigned
FILING DATE: November 12, 2003 ART UNIT: Not yet assigned
FOR: DETECTING GENETIC PREDISPOSITION TO SIGHT THREATENING
DIABETIC RETINOPATHY

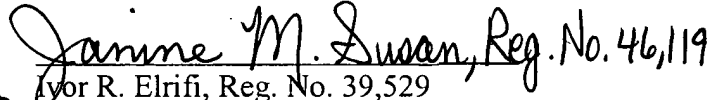
Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT AND ACCOMPANYING
FORM PTO-1449**

Applicants submit herewith a copy of modified Pto-1449 form submitted in parent application USSN 09/037,472 from which the presently filed application claims priority. Copies of the references listed therein are not enclosed but will be provided upon request. Applicants request that each of the listed documents be made part of the record in the presently filed application.

The Information Disclosure Statement is being submitted concurrently with the filing of the application. Accordingly, no fee is believed due. However, the Commissioner is authorized to charge any fees due, or credit over payments of same to Deposit Account No. 50-0311, Ref. No. 24299-506CON.

Respectfully submitted,

for  Janine M. Susan, Reg. No. 46,119
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Dated: November 12, 2003

In re Application of

Application No.: 09/037,472

Title: Detecting Genetic Predisposition to Sight-Threatening Diabetic Retinopathy

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**Group Art Unit: Unassigned**

**Examiner:** Unassigned

Atty. Dkt. No.: 33174.73

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents,  
Washington, D.C. 20231

on September 21, 1998

**Signature**

NANCY STACEY

## INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement, including completed Form PTO-1449, comprises a list of pertinent art of which applicants are aware. A copy of each publication listed on Form PTO-1449 is enclosed herewith. The submission of this Information Disclosure Statement and Form PTO-1449 is not an admission that the art cited is "prior" with respect to the present invention, nor is it a representation that no better art exists. Applicants hereby reserve the right to swear behind or otherwise disprove any alleged "prior" nature of any art cited should the facts support and the situation warrant such an action.

It is submitted that the art cited does not constitute a bar to the patentability of Applicants' invention under 35 U.S.C. § 102 or § 103.

In the event that an Office Action dated prior to the mailing of this Information Disclosure Statement has been issued, please charge Deposit Account 10-0447 in the amount of \$240.00, so that this Information Disclosure Statement may be considered under Rule 1.97(c).

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Tamsen Valoir', is written over a horizontal line.

Tamsen Valoir, Ph.D.

Registration No. 41,417

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Date: September 21, 1998

Form PTO-1449 (Modified)

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT**

(Use several sheets if necessary)

Atty. Docket  
No.33174-73Serial No.  
09/037,472Applicant  
Duff, et al.Filing Date  
03/10/98

Group

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

| EXAMINER<br>INITIAL |    | DOCUMENT<br>NUMBER | DATE     | NAME                  | CLASS | SUB-<br>CLASS | FILING DATE IF<br>APPROPRIATE |
|---------------------|----|--------------------|----------|-----------------------|-------|---------------|-------------------------------|
|                     | AA | 5,039,606          | 8/13/91  | Nepon                 | 435   | 6             | 10/29/87                      |
|                     | AB | 5,196,308          | 3/23/93  | Nepom <i>et al.</i>   | 435   | 7.21          | 03/13/89                      |
|                     | AC | 5,686,246          | 11/11/97 | Kornman <i>et al.</i> | 435   | 6             | 080/3/95                      |
|                     | AD | 5,698,399          | 12/16/97 | Duff <i>et al.</i>    | 435   | 6             | 04/05/96                      |

## FOREIGN PATENT DOCUMENTS

|  |  | DOCUMENT<br>NUMBER | DATE | COUNTRY | CLASS | SUB-<br>CLASS | Translation |    |
|--|--|--------------------|------|---------|-------|---------------|-------------|----|
|  |  |                    |      |         |       |               | YES         | NO |
|  |  |                    |      |         |       |               |             |    |

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

|  |    |                                                                                                                                                                                     |
|--|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | AE | Adamis, <i>et al.</i> "Increased Vascular..." <i>Am. J. Ophthalmol.</i> 118(4): 445 (Oct. 1994)                                                                                     |
|  | AF | Aiello, <i>et al.</i> , "Vascular Endothelial Growth ..." <i>N.E.J.M.</i> 331(22): 1480 (Dec. 1994)                                                                                 |
|  | AG | Author unknown, excerpt from publication (no title); first heading: "What is Diabetes?"; Citation unknown                                                                           |
|  | AH | Blakemore, <i>et al.</i> , <i>Hum. Genet.</i> 97(3): 369-74 (1996)                                                                                                                  |
|  | AI | Blakemore, <i>et al.</i> , <i>Arthritis Rheum.</i> 37: 1380-85 (1994)                                                                                                               |
|  | AJ | Center for Disease Control and Prevention, the, "National Diabetes Fact Sheet" (Nov. 1995)                                                                                          |
|  | AK | Clark, <i>et al.</i> , <i>Nuc. Acids Res.</i> 14: 7897 (1986); Erratum in <i>Nuc. Acids Res.</i> 15(2): 868 (1987)                                                                  |
|  | AL | Clay <i>et al.</i> , "Interleukin-1 receptor antagonist gene polymorphism association with lichen scleroses", <i>Hum. Genet.</i> 94: 407-410 (1994)                                 |
|  | AM | Clay <i>et al.</i> , "Novel interleukin-1 receptor antagonist exon polymorphisms and their use allele-specific mRNA assessment", <i>Human Genetics</i> 97(6): 723-726 (June 1996)   |
|  | AN | Cork, <i>et al.</i> , <i>J. Invest. Dermatol.</i> 104(5 Supp.): 15S-16S (1995)                                                                                                      |
|  | AO | di Giovine <i>et al.</i> , "Single base polymorphism at -511 in the human interleukin-1 $\beta$ gene (IL1 $\beta$ )", <i>Human Molecular Genetics</i> 1(6):410 Abstract only (1992) |
|  | AP | Dinarelli, "Interleukin-1 and Interleukin-1 Antagonism" <i>Blood</i> 77: 1627 (1991)                                                                                                |
|  | AQ | DRS Report No. 7 "A Modification of the ..." <i>Invest. Ophthalmol. Vis. Sci.</i> 21: 210 (1981)                                                                                    |
|  | AR | DRS Report No. 8 "Photocoagulation Treatment of ..." <i>Ophthalmol.</i> 88(7): 583 (1981)                                                                                           |
|  | AS | Duff, "Cytokines and Anti-Cytokines" <i>Br. J. Rheumatol.</i> 31(Supp. 1): 15 (1993)                                                                                                |
|  | AT | Duff, "Molecular Genetics of Cytokines", <i>The Cytokine Handbook</i> (1994) 2nd ed., Chap. 2: 21-30.                                                                               |
|  | AU | ETDRS No. 1, "Photocoagulation for diabetic Macula Edema" <i>Arch. Ophthalmol.</i> 103: 1796 (1993)                                                                                 |

Form PTO-1449 (Modified)

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE  
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03/10/98

Group

|  |    |                                                                                                                                                                                                                               |
|--|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | AV | ETDRS No. 9, "Early Coagulation..." <i>Ophthalmol.</i> 98: 766 (1991)                                                                                                                                                         |
|  | AW | ETDRS No. 12, "Fundus Photographic Risk..." <i>Ophthalmol.</i> 98: 823 (1991)                                                                                                                                                 |
|  | AX | Franks, et al., "Cytokines in Human ..." <i>Current Eye Res.</i> 11(Supp.): 187 (1992)                                                                                                                                        |
|  | AY | Furutani et al., "Complete Nucleotide Sequence" <i>Nuc. Acids Res.</i> 14: 3167 (1992)                                                                                                                                        |
|  | AZ | Hu, et al., "Inhibition of Angiogenesis..." <i>Inflammation</i> 18(1): 45 (1994)                                                                                                                                              |
|  | BA | Hu & Fan "Protein Kinase C Inhibitor..." <i>Inflammation</i> 19(1): 39 (1995)                                                                                                                                                 |
|  | BB | Klein et al., "Self-Rates Health and Diabetes of Long Duration," <i>Diabetes Care</i> , 21(2): 236-240 (Feb. 1998)                                                                                                            |
|  | BC | Ko et al., "An (A-C) <sub>n</sub> Dinucleotide Repeat Polymorphic Marker at the 5' End of the Aldose Reductase Gene Is Associated With Early-Onset Diabetic Retinopathy in NIDDM Patients", <i>Diabetes</i> 44:727-732 (1995) |
|  | BD | Mansfield et al., "Novel Genetic Association Between Ulcerative Colitis and the Anti-Inflammatory Cytokine Interleukin-1 Receptor Antagonist", <i>Gastroenterology</i> 106: 637-642 (Mar. 1994)                               |
|  | BE | McCarren, "Genetics of Diabetes", Publication American Diabetes Association                                                                                                                                                   |
|  | BF | Murata, et al., "Vascular Endothelial Growth ..." <i>Ophthalmic Res.</i> 27(1): 48 (1995)                                                                                                                                     |
|  | BG | Nedospasov, et al., "Tandem Arrangement of Genes ..." <i>Cold Spring Harbor Sympos. Quant. Biol.</i> 60: 611 (1986)                                                                                                           |
|  | BH | Nicklin, et al., <i>Genomics</i> 19: 382-4 (1994).                                                                                                                                                                            |
|  | BI | PCT Search Report, citing Mansfield; Ko and Richardson                                                                                                                                                                        |
|  | BJ | Pe'er, et al., "Hypoxia-Induced Expression of ..." <i>Lab. Invest.</i> 72(6): 638 (June 1995)                                                                                                                                 |
|  | BK | Pfeiffer, "Vascular Endothelial Growth ..." <i>Dtsch. Med. Wochenschr.</i> 120(42): 1453 (Oct. 1995)                                                                                                                          |
|  | BL | Pociot, et al., <i>Eur J. Clin. Invest.</i> 22: 396-402 (1992)                                                                                                                                                                |
|  | BM | Richardson, et al., <i>Invest. Ophthalmol.</i> 38(4): 3714 (1997)                                                                                                                                                             |
|  | BN | Seaquist, et al., "Familial Clustering of ..." <i>N.E.J.M.</i> 320: 1161 (1989)                                                                                                                                               |
|  | BO | Tarlow, et al., <i>J. Invest. Dermatol.</i> 103: 387 (1994)                                                                                                                                                                   |
|  | BP | Todd, "Genetic Control of ..." <i>Immunol. Today</i> 11:122 (1990)                                                                                                                                                            |
|  | BQ | Verjans, et al., "Polymorphism of the TNF Region in ..." <i>Rheum. Dis. Clin. North Am.</i> 18: 177 (1992)                                                                                                                    |
|  | BR | Woolf, "Estimating the Relationship between Blood Groups & Disease" <i>Annals Human Genet.</i> 19: 251 (1955)                                                                                                                 |